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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/039,956	10/23/2001	Melissa K. Carpenter	091/009C	1602

22869 7590 09/23/2003

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EXAMINER

TON, THAIAN N

ART UNIT

PAPER NUMBER

1632

DATE MAILED: 09/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/039,956	CARPENTER ET AL.	
	Examiner	Art Unit	
	Thái-An N. Ton	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 and 30-36 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-22, 30-36 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-3, 7, 9 and 32, drawn to compositions comprising primate pluripotent stem [pPS] cells, classified in class 435, subclass 325, 363, 366, for example.
- II. Claim 4, drawn to a method for culturing primate pluripotent stem cells in a growth environment free of feeder cells, classified in class 435, subclass 363, 366, 383, for example.
- III. Claims 5 and 6, drawn to methods for producing a conditioned medium and conditioned medium, classified in class 435, subclass 383, 391, for example.
- IV. Claims 8 and 15 drawn to a differentiated human cell lines, classified in class 435, subclass 325, 366, for example.
- V. Claims 10-14 and 35, drawn to methods for producing a differentiated cell population, classified in class 435, subclass 363, 366, 377, for example.
- VI. Claim 16, drawn to a method of screening a compound for cellular toxicity or modulation, classified in class 435, subclass 4, for example.
- VII. Claim 17, drawn to a method for producing a polynucleotide sequence contained in an mRNA that is expressed at a different level in committed or differentiated cells compared with undifferentiated pPS cells, classified in class 435, subclass 455, for example.
- VIII. Claims 18-21, drawn to method for producing genetically altered primate pluripotent stem cells and genetically altered pPS cells classified in class 435, subclass 455, 325.
- IX. Claim 22, drawn to a population of genetically altered differentiated cells, classified in class 435, subclass 455.

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- X. Claim 30, drawn to a method for producing a protein containing a sequence of a polypeptide expressed in undifferentiated or differentiated pPS cells, classified in class 435, subclass 69.1, for example.
- XI. Claim 31, drawn to a method for producing an antibody specific for a polypeptide expressed in undifferentiated or differentiated pPS cells, classified in class 435, subclass 69.1, class 530, subclass 387.1, for example.
- XII. Claims 33, 34 and 36, drawn to methods for establishing a line of human ES cells, classified in class 435, subclass 366, for example.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and any of Inventions II, IV, V, VI, VIII, X, XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the compositions comprising pPS cells can be used in methods of cell therapy, or methods of nuclear transfer.

Inventions I and any of III, VII, IX or XII are mutually exclusive and independent inventions. The composition of pPS cells of Invention I are not required for the implementation of the methods for producing a conditioned medium and conditioned medium of Invention III, the method for producing a polynucleotide sequence contained in an mRNA that is expressed at a different level in committed or differentiated cells compared with undifferentiated pPS cells of Invention VII,

the population of genetically altered differentiated cells of Invention IX, or the methods of establishing a line of human ES cells of Invention XII, and vice versa.

Inventions II and any of Inventions III-XII are mutually exclusive and independent methods. The method for culturing pPS cells of Invention II is not required for the methods for producing a conditioned medium of Invention III, the differentiated human cell lines of Invention IV, the methods for producing a differentiated cell population of Invention V, the method of screening a compound for cellular toxicity or modulation of Invention VI, the method for producing a polynucleotide sequence contained in an mRNA that is expressed at a different level in committed or differentiated cells compared with undifferentiated pPS cells of Invention VII, the method for producing genetically altered primate pluripotent stem cells and genetically altered pPS cells of Invention VIII, the population of genetically altered differentiated cells of Invention IX, the method for producing a protein containing a sequence of a polypeptide expressed in undifferentiated or differentiated pPS cells of Invention X, the method for producing an antibody specific for a polypeptide expressed in undifferentiated or differentiated pPS cells of Invention XI and the methods for establishing a line of human ES cells of Invention XII, and vice versa. Furthermore, each of the methods requires a materially different and separate protocol.

Inventions III and any of Inventions IV-XII are mutually exclusive and independent. The methods for producing a conditioned medium of Invention III are

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not required for the implementation of the differentiated human cell lines of Invention IV, the methods for producing a differentiated cell population of Invention V, the method of screening a compound for cellular toxicity or modulation of Invention VI, the method for producing a polynucleotide sequence contained in an mRNA that is expressed at a different level in committed or differentiated cells compared with undifferentiated pPS cells of Invention VII, the method for producing genetically altered primate pluripotent stem cells and genetically altered pPS cells of Invention VIII, the population of genetically altered differentiated cells of Invention IX, the method for producing a protein containing a sequence of a polypeptide expressed in undifferentiated or differentiated pPS cells of Invention X, the method for producing an antibody specific for a polypeptide expressed in undifferentiated or differentiated pPS cells of Invention XI and the methods for establishing a line of human ES cells of Invention XII, and vice versa. Furthermore, each of the methods requires a materially different and separate protocol.

Inventions IV and V are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the differentiated cells can be made

by isolation of the cells from an organ. For example, fibroblasts can be isolated from skin.

Inventions IV and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the differentiated cells can be used for cellular therapy or as a donor in a nuclear transfer method.

Invention IV and any of Inventions VII-XII are independent inventions. The differentiated human cell lines of Invention IV are not required for the implementation of the method for producing a polynucleotide sequence contained in an mRNA that is expressed at a different level in committed or differentiated cells compared with undifferentiated pPS cells of Invention VII, the method for producing genetically altered primate pluripotent stem cells and genetically altered pPS cells of Invention VIII, the population of genetically altered differentiated cells of Invention IX, the method for producing a protein containing a sequence of a polypeptide expressed in undifferentiated or differentiated pPS cells of Invention X, the method for producing an antibody specific for a polypeptide expressed in undifferentiated or differentiated pPS cells of Invention XI and the methods for establishing a line of human ES cells of Invention XII, and vice versa.

Invention V and Invention VI are distinct methods. The methods of for producing a differentiated cell population of Invention V have different technical considerations and practice a materially different and separate protocol from the methods of screening a compound for cellular toxicity or modulation of Invention VI.

Invention V and any of Inventions VII-XII are independent inventions. The methods for producing a differentiated cell population of Invention V are not required for the implementation of the method for producing a polynucleotide sequence contained in an mRNA that is expressed at a different level in committed or differentiated cells compared with undifferentiated pPS cells of Invention VII, the method for producing genetically altered primate pluripotent stem cells and genetically altered pPS cells of Invention VIII, the population of genetically altered differentiated cells of Invention IX, the method for producing a protein containing a sequence of a polypeptide expressed in undifferentiated or differentiated pPS cells of Invention X, the method for producing an antibody specific for a polypeptide expressed in undifferentiated or differentiated pPS cells of Invention XI and the methods for establishing a line of human ES cells of Invention XII, and vice versa.

Invention VI and any of Inventions VII-XII are mutually exclusive and independent inventions. The method for producing a polynucleotide sequence contained in an mRNA that is expressed at a different level in committed or differentiated cells compared with undifferentiated pPS cells of Invention VII are not required for the implementation of the method for producing genetically altered

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primate pluripotent stem cells and genetically altered pPS cells of Invention VIII, the population of genetically altered differentiated cells of Invention IX, the method for producing a protein containing a sequence of a polypeptide expressed in undifferentiated or differentiated pPS cells of Invention X, the method for producing an antibody specific for a polypeptide expressed in undifferentiated or differentiated pPS cells of Invention XI and the methods for establishing a line of human ES cells of Invention XII, and vice versa. Furthermore, each of the methods requires a materially different and separate protocol.

Invention VII and any of Inventions VIII-XII are mutually exclusive and independent inventions. The method for producing genetically altered primate pluripotent stem cells and genetically altered pPS cells of Invention VIII are not required for the population of genetically altered differentiated cells of Invention IX, the method for producing a protein containing a sequence of a polypeptide expressed in undifferentiated or differentiated pPS cells of Invention X, the method for producing an antibody specific for a polypeptide expressed in undifferentiated or differentiated pPS cells of Invention XI and the methods for establishing a line of human ES cells of Invention XII, and vice versa. Furthermore, each of the methods requires a materially different and separate protocol.

Inventions VIII and IX are distinct. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can

be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the genetically altered differentiated cells can be made by electroporation of DNA into differentiated cells.

Inventions VIII and any of Inventions X-XII are independent. The methods for producing genetically altered differentiated cells of Invention VIII are not required for the implementation of the method for producing a protein containing a sequence of a polypeptide expressed in undifferentiated or differentiated pPS cells of Invention X, the method for producing an antibody specific for a polypeptide expressed in undifferentiated or differentiated pPS cells of Invention XI and the methods for establishing a line of human ES cells of Invention XII, and vice versa. Furthermore, each of the methods requires a materially different and separate protocol.

Inventions IX and any of Inventions X-XII are mutually exclusive and independent inventions. The genetically altered differentiated cells of Invention IX are not required for the implementation of the method for producing a protein containing a sequence of a polypeptide expressed in undifferentiated or differentiated pPS cells of Invention X, the method for producing an antibody specific for a polypeptide expressed in undifferentiated or differentiated pPS cells of Invention XI, the methods for establishing a line of human ES cells of Invention XII, and vice versa.

Invention X and either of Inventions XI or XII are mutually exclusive and independent inventions. The method for producing a protein containing a sequence of a polypeptide expressed in undifferentiated or differentiated pPS cells of Invention X is not required for the implementation of the method for producing an antibody specific for a polypeptide expressed in undifferentiated or differentiated pPS cells of Invention XI, and the methods for establishing a line of human ES cells of Invention XII, and vice versa.

Inventions XI and XII are mutually exclusive and independent inventions. The method for producing an antibody specific for a polypeptide expressed in undifferentiated or differentiated pPS cells of Invention XI are not required for the implementation of the methods for establishing a line of human ES cells of Invention XII, and vice versa. Each of the methods requires a materially different and separate protocol.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if

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one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thái-An N. Ton whose telephone number is (703) 305-1019. The examiner can normally be reached on Monday through Friday from 8:00 to 5:00 (Eastern Standard Time), with alternating Fridays off. Should the examiner be unavailable, inquiries should be directed to Deborah Reynolds, Supervisory Primary Examiner of Art Unit 1632, at (703) 305-4051. Any administrative or procedural questions should be directed to William Phillips, Patent Analyst, at (703) 305-3482. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703)-872-9306.

TNT

Thái-An N. Ton
Patent Examiner
Group 1632



AU 1632